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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,037	07/23/2003	Warren J. Scherer	512-160	1255

7590 04/30/2010  
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EXAMINER
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ROYDS, LESLIE A

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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04/30/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	<b>Application No.</b> 10/626,037	<b>Applicant(s)</b> SCHERER, WARREN J.	
	<b>Examiner</b> Leslie A. Royds	<b>Art Unit</b> 1614	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 05 April 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
 b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: \_\_\_\_\_.  
 Claim(s) objected to: 12.  
 Claim(s) rejected: 11, 12 and 36.  
 Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
 12. ☐ Note the attached Information *Disclosure Statement(s)*. (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
 13. ☐ Other: \_\_\_\_\_.

/Leslie A. Royds/  
 Primary Examiner, Art Unit 1614

Continuation of 3. NOTE:

Applicant's proposed after-final amendment filed April 5, 2010 will not be entered into the record because the entry of such an amendment raises new issues that would require further consideration and/or search.

In particular, Applicant proposes limiting instant claim 36 to wherein the composition comprises an effective amount "of a single active component that reduces cutaneous facial flushing, wherein the single active component consists of brimonidine tartrate". Such an amendment clearly raises a new issue that necessitates further consideration and/or search to determine the manner in which the term "active" has been defined in the instant disclosure. In addition, the addition of the word "active" in instant claim 36 raises a new issue under 35 USC 112, second paragraph, regarding vagueness and indefiniteness because the claims fail to clearly set forth the identity of the activity. For example, it is unclear if the "activity" of the component is its ultimate physiological effect on facial flushing or if it is the mechanism by which the compound functions to treat the facial flushing (i.e., that the compound functions as an alpha-2 adrenergic receptor agonist). In addition, this ambiguity in the claims is further complicated by the fact that instant claim 11 further provides for the use of other agents that clearly possess an "activity" in the sense that they are, e.g., antibacterial agents, antioxidant agents, etc. The presence of such additional components confuses the determination of what would be considered an "active component" of the claims and what would not be considered an "active" component of the claims. As a result, entry of the proposed after-final amendment would necessitate further consideration and/or search, as well as would require additional assessments of the prior art to determine whether additional prior art would be applicable to the claims, which are also considered new issues. Accordingly, the amendments will not be entered into the record.

In addition, the proposed claim amendments are not deemed to place the application in better form for appeal by materially reducing to simplifying the issues for appeal because they raise new issues that require further consideration and/or search.

Continuation of 11. does NOT place the application in condition for allowance because:

Applicant's request for reconsideration of the present application with regard to the rejections and/or objections of record in light of the amendments to the claims proposed and presented in the after-final amendment has been made. In light of the fact that the proposed amendments to the claims will not be entered into the record, Applicant's remarks directed to the obviation of these rejections and/or objections as a result of the proposed amendments are not found persuasive.

For these reasons supra, the proposed amendments will not be entered into the record and the claims remain rejected for the reasons set forth in the final rejection dated February 3, 2010, of which said reasons are herein incorporated by reference.

/Leslie A. Royds/  
Primary Examiner, Art Unit 1614.